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|   |             |                      |                           |                  |
|---|-------------|----------------------|---------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.       | CONFIRMATION NO. |
| 09/898,887  | 07/03/2001  | Raghavan Rajagopalan | MRD-61                    | 2188             |
| 26875 7590 01/10/2007<br>WOOD, HERRON & EVANS, LLP<br>2700 CAREW TOWER<br>441 VINE STREET<br>CINCINNATI, OH 45202 |             |                      | EXAMINER<br>LUKTON, DAVID |                  |
|   |             |                      | ART UNIT<br>1654          | PAPER NUMBER     |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             |                      | MAIL DATE                 | DELIVERY MODE    |
| 3 MONTHS  |             |                      | 01/10/2007                | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

09/898,887

**Applicant(s)**

RAJAGOPALAN ET AL.

**Examiner**

David Lukton

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-28,30,31,35,36 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-28,30,31,35,36 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/24/06 has been entered.

Pursuant to the directives of the response filed 10/24/06, claim 15 has been amended. Claims 15-28, 30, 31, 35, 36, 47 remain pending. Applicants arguments filed 10/24/06 have been considered and found persuasive in part.



Claim 15 is objected to. Clarity would be enhanced if the definition of each of the substituent variables began on a new line, i.e., the following format:

*wherein E is dihydroxyindolecarboxylic acid;*

*X is selected from the group consisting of ...;*

*R<sup>1</sup> is selected from the group consisting of ...;*

*R<sup>2</sup> is selected from the group consisting of ...;*

*R<sup>3</sup> is selected from the group consisting of ...;*

*R<sup>4</sup> is selected from the group consisting of ...;*

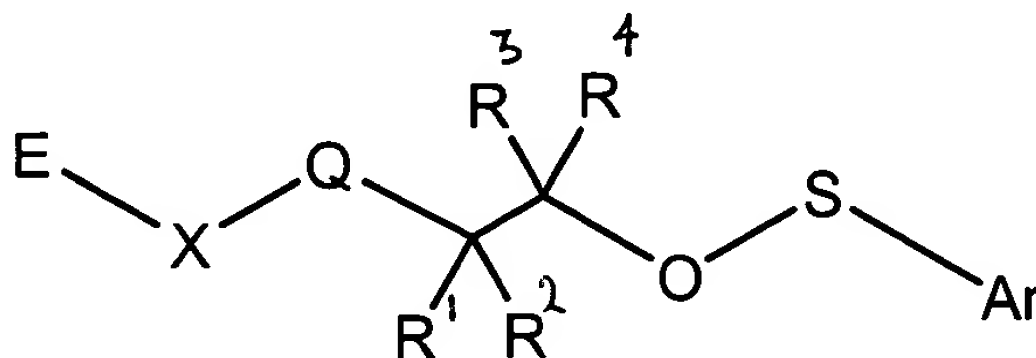
*R<sup>5</sup> is selected from the group consisting of ...;*

*Q is ... ..*



Claims 15-28, 30, 31, 35, 36, 47 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In the structural formula that is recited in claim 15, a series of four hyphens is used to denote each of the covalent bonds. However, this is at odds with conventional denotations. The four hyphens (in each case) should be replaced with a single line. Alternatively, the following format can be used:



- Claim 15 recites the following:

“...which comprises... administering ... a ... photosensitizer in a topical formulation with at least one excipient having the formula...”

This language tends to convey that it is the excipient which has the indicated formula, rather than the photosensitizer. One option would be language such as the following:

*A method of performing a photosensitizing procedure which comprises the steps of (a) topically administering to the skin of a mammal a pharmaceutically acceptable formulation that comprises at least one excipient and a sulfonate photosensitizer having the formula:*

- In claim 15, second-to-last line, the phrase “target tissue” lacks antecedent basis.
- Claim 15 calls for administering the formulation to the skin of an animal. However,

it is not apparent how one should proceed if the location of the skin is not readily discernable. For example if the animal in question is an echinoderm, a sea sponge, a mollusk, a sea anemone or an insect, how would one proceed?

- In claims 16, 30, 31, 35, the phrase "target tissue" lacks antecedent basis.
- Claim 30 recites that the amount which is "administered to the target tissue" can be as high as 500 mg/kg body weight. Given that the compound is to be administered only to the skin, and no other tissue, it is unclear what is meant by this.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER